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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/746,670	12/22/2000	Shanta M. Modak	A33432 070050.1354	1401

21003 7590 02/13/2004

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EXAMINER	
BENNETT, RACHEL M	
ART UNIT	**PAPER NUMBER**
1615	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/746,670	MODAK ET AL.	
	Examiner	Art Unit	
	Rachel M. Bennett	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the c rrespondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13, 17-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 17-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/29/03 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-2, 8-9, 17, 21-22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 09/746658. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications claim a polymeric medical article impregnated with a treatment solution comprising chlorhexidine free base and a chlorhexidine salt. Also, the methods of preparing the article are both drawn to (i) placing the medical article in a solution of comprising (a) a solvent and (b) a mixture of chlorhexidine free base and

chlorhexidine salt in a 1:1 ratio and 1:5 weight/weight ratio, (ii) soaking the medial article for an effective amount of time, (iii) removing the article from the solution and (iv) drying the medical article.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Specification

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 1-3, 8-13, 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al. (US 621271).

Solomon discloses an anti-infective medical article has chlorhexidine bulk distributed throughout a polyurethane base layer and may have a coating layer on the base layer. The coating layer may be chlorhexidine permeated into the surface or it may be an antibiotic, antithrombogenic agent or a polymeric surface layer laminated into the base layer (see abstract). Preferred articles are polymeric, most preferably a hydrophilic polymeric vascular assess catheter (see col. 4 line 6-7). The chlorhexidine may be melted or may be a solid uniformly distributed in the polymer melt. The melt to be extruded by contain about 0.05% to 10%, preferably about 1 to 5% by weight of chlorhexidine, and may be prepared in any suitable way (see col. 4 lines 56-61). The article having bulk distributed chlorhexidine may be steeped in a solvent solution of

chlorhexidine to permeate a layer of chlorhexidine into the surface of the article. An effective coating of chlorhexidine may be obtained when the steeping solution contains from about 1-25%, preferably 5-15% of chlorhexidine. Accordingly, the choice of solvent depends on the form of chlorhexidine being coated and on the temperature contemplated for the steeping solution. Suitable solvents to serve as the steeping medium for chlorhexidine base are water, methylene chloride and preferably methanol. For chlorhexidine salts, such as the hydrochloride, acetate, or preferably the gluconate, suitable solvents are methanol, ethanol, and preferably water. Steeping may be carried out for about 2 minutes to 2 hours at a temperature of about 15 to 60 deg. C. It is, of course, evident that a chlorhexidine coating may be formed on either of both the outside and lumen walls of the catheter merely by contacting the desired walls with the steeping solution. Thus, steeping solution may be drawn into the lumen for contact with the lumen wall only, or the lumen may be filled with a solid rod so that the steeping solution contacts only the outside wall (see cols 5-6). Solomon does not disclose the weight/weight ratio of chlorhexidine free base and water-soluble chlorhexidine salt in the solution is between 1:1 to 1:5.

Absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined a suitable % weight of the chlorhexidine free base and water-soluble chlorhexidine salt. Differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical.

6. Claims 1-13, 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solomon et al. (US 621271) in further view of the Merck Index.

Solomon, as disclosed above, teaches an anti-infective medical article has chlorhexidine bulk distributed throughout a polyurethane base layer and may have a coating layer on the base layer. Solomon does not disclose the solvent to be tetrahydrofuran.

The Merck Index discloses tetrahydrofuran as a solvent for high polymers. Furthermore, tetrahydrofuran is miscible with water, alcohols, ketones, esters, ethers and hydrocarbons.

Absent unexpected results, it would have been obvious to one of ordinary skill in the art the time the invention was made to have modified the composition of Solomon by adding tetrahydrofuran taught by the Merck Index with the solvents taught by Solomon, because tetrahydrofuran a known solvent used for polymers and is miscible with water and alcohols as taught by the Merck Index.

Response to Arguments

7. Applicant's arguments filed 12/29/03 have been fully considered but they are not persuasive.

Applicants argue the '271 patent does not disclose, teach or suggest an antimicrobial medical article prepared by treating a polymeric medical article with a solution consisting essentially of one of more solvents and a mixture of chlorhexidine free base and water-soluble chlorhexidine salt, wherein the weight/weight ratio of chlorhexidine free base and water soluble chlorhexidine in solution is between 1:1 to 1:5. The examiner refers to '271 wherein Solomon teaches the article having bulk distributed chlorhexidine may be steeped in a solvent solution of chlorhexidine to permeate a layer of chlorhexidine into the surface of the article. An effective coating of chlorhexidine may be obtained when the steeping solution contains from about 1-25%, preferably 5-15% of chlorhexidine. Accordingly, the choice of solvent depends on the form of

chlorhexidine being coated and on the temperature contemplated for the steeping solution. Furthermore, absent unexpected results, it is the position of the examiner it would have been obvious to one of ordinary skill in the art at the time the invention was made to have determined a suitable % weight of the chlorhexidine free base and water-soluble chlorhexidine salt. Differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Applicants also argue the preferred embodiment disclosed in '271 lack the appreciation of the synergy between chlorhexidine free base and chlorhexidine salt as an antimicrobial agent. The standard for 103 is not whether a preferred embodiment discloses the invention, but rather is the reference in its entirety discloses the limitations. It is the position of the examiner, '271 discloses the limitations claimed by Applicants. Lastly, Applicants argue the instant specification distinguishes bulk distributed chlorhexidine from the claimed invention in that bulk distributed manufacturing methods adversely affect certain characteristics (e.g., tensile strength) of the medical article, and the high temperatures involved in such methods may reduce the specific activity of the bulk distributed chlorhexidine. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., tensile strength and temperature) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. Therefore the rejections under 103(a) have been maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel M. Bennett whose telephone number is (571) 272-0589. The examiner can normally be reached on Monday through Friday, 8:00 A.M. to 4:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

rmb

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GROUP 1500